Medical Devices:
Marketing Your Skills and Ideas

Dennis Falkenstein
September 15, 2009
Outline

- Short History of Medical Innovations
- Medical Business or Information Business?
- Cost Containment as a Driver
- You Have an Innovative Device, Now What?
- Market Plan to Business Plan
- Medical Market Specifics
What this lecture is NOT

- Town Hall Meeting to promote National Health Care
- Tea Party in opposition to National Health Care
Democratic Health Care Plan
Republican Alternative
The Real Medical Tea Party 1846
Ether and the Beginnings of Exploratory Surgery 1846
1972 CT Scan 1979 Nobel Laureate to Hounsfield, EMI

I’m Looking Through You
Plethora of ancillary devices
The bionic contact lens
Innovations in Imaging

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THURSDAY, AUGUST 15, 2002

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To Avoid Surgery, Eat This Camera

More Doctors Get Inside View Of the Body With Video Pill; Close-Ups of a Tumor Site

By Marilyn Chase

Kristen Parise was tired of not knowing what was wrong with her. The 39-year-old homemaker was dangerously anemic from internal bleeding and had undergone a colonoscopy, barium X-rays and six other unconvincing or even surgery to figure out what is wrong. The problems that can strike include ulcers, tumors, leaky vessels and inflammatory conditions like Crohn’s disease and irritable bowel syndrome. But the upper intestine is hard to see with conventional imaging tools. “The 22 feet between the stomach and colon has been a black box,” says Gabriel Meron, chief executive of Gavriel Imaging Inc., the Yooqan, Israel, company that makes the technology. The tiny disposable camera-like pill, lower in the gut, can see the entire length of the intestinal tract in 24 states, and those with Medicare coverage, plus Washington, D.C., Puerto Rico and the U.S. Virgin Islands. Because it is new, the video pill is mostly used after conventional tests have failed., says Hollyn Chisholm Greer of University Hospital in Salt Lake City. It already has cleared the mystery of internal bleeding whose source is unknown.

Capsule endoscopy is “an amazing technology,” says Ms. Parise’s surgeon, Gregg Jassart. He sees a number of patients like Ms. Parise for whom “it will mean quicker diagnosis and cure.”

Ms. Parise swallowed the smooth plastic capsule, which is like an overtime vitamin, and demed a thick Velcro belt loaded with a battery pack and a Wallman-size recording device. Electronic leads were attached to her torso. Over the next eight hours, she was free to stroll, eat or drink as the device meandered through her body, taking 60,000 flash pictures—two per second—and transmitting the pictures to the recording device. The single-use capsule passed out painlessly after 24 hours.

Then she returned the gear she had worn to her hospital, California Pacific Medical Center in San Francisco, where gastroenterologist Kenneth Blumstedt and nurse Marthe Mattson loaded the data recorder onto a workstation.

‘Fantastic Voyage’

On the screen, views of her body’s interior unfolded like scenes from the 1966 sci-fi film “Fantastic Voyage,” where doctors explore the body in a tiny submarine. Her intestine, a pulsing, writhing tunnel, was stained with resemblance to the canals on Mars.

“Wow,” said Ms. Mattson while refilling the video, freezing a frame, 33 minutes and 16 seconds
Knowledge for decision assistance

- Early work in area of EKG analysis by computer
- Cardiac ejection fraction calculations
- Mammography reading assistance
- Care Flow
- Contraindications of drugs
Medical business is really information, or...
Institute of Medicine 2001
IOM Resources

CROSSING THE QUALITY CHASM
A New Health System for the 21st Century

KNOWING WHAT WORKS IN HEALTH CARE
A ROADMAP FOR THE NATION

HEALTH LITERACY, eHEALTH, and COMMUNICATION
PUTTING THE CONSUMER FIRST
Short History

- Non Invasive Diagnosis and Treatment
  - X-ray imaging, CT scanner, MRI, pharmaceuticals
- Cellular imaging or DNA indicators
- ATM laboratory
- Or?
The Future Clinical Lab?
The Business Plan

- Essential element of any business
- Necessary for raising capital
- Necessary to determine direction of company; mission, vision
- Reference of measure of progress
- Points to alternative directions (Plan B)
Elements of a Business Plan

- Description of company and product/service offering
- Market Plan
- Revenue projections
- Operation expenses
- Results/Profits/Milestones
- Management team
- Supporting Documents
Elements of a Business Plan

- Description of company and product/service offering
- **Market Plan**
  - Revenue projections
  - Operation expenses
  - Result/Profits
  - Management team
- Supporting Documents
Market plan

- Answers the feasibility of business
- Based on market needs/wants
- Product value
- Market size
- Reimbursement issues
- Regulatory issues
- Market sustainability
- Distribution/sales channel
- Competition
- Replacement technology
- Risks, SWAT, PEST
Specifics of medical market

- Well defined customer universe
- Well defined usage requirements
- Price determined by LCA (Lowest Cost Alternative)
- Regulatory compliance
  - Most medical devices require FDA review (clearance or approval)
  - HIPAA requirements; Health Insurance Portability and Accountability Act
  - Sarbanes-Oxley; SOX
Various medical engagements

- Medical device to end user
- Accessories to medical device
- Software for medical device or application
- Subsystems for medical device
- Components of medical device
Complexity varies with various engagements

Reimbursement

- Medical device to end user
- Accessories to medical device
- Software for medical device
- Subsystems for medical device
- Components of medical device

<table>
<thead>
<tr>
<th>Regulatory Involvement</th>
<th>Cost Constraints</th>
<th>Driven</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGHEST</td>
<td>LOWEST</td>
<td>HIGHEST</td>
</tr>
<tr>
<td>LOWEST</td>
<td>HIGHEST</td>
<td>LOWEST</td>
</tr>
</tbody>
</table>
Various medical engagements

- Medical device to end user
- Accessories to medical device
- Software for medical device or application
- Subsystems for medical device
- Components of medical device
Specifics of medical market

- Well defined customer universe
  - Hospitals
  - Clinics
  - Private physicians
  - Nursing homes
  - Home market
Specifics of medical market

• Well defined customer universe
  • Hospitals
  • Clinics
  • Private physicians
  • Nursing homes
  • Home market
Determinants of device selling price

- Medical market is NOT cost plus
- Need to determine the value of your device and it must be greater than the cost of your product; include all costs; direct and indirect
- Selling price as a function of the value;
  - More patients per unit time
  - Less labor per procedure
  - Less errors per procedure
  - Less complications or morbidity
  - Higher cure rate
Macro approach

- National incidence numbers on disease
  - Specific segmentation of disease
  - Cure rates, diagnostic specificity and sensitivity
  - Complications
  - Care flow
- Costs for care
- Reimbursement levels
Specifics of medical market

- Well defined usage requirements
  - Volume data available on many diseases and treatments
  - Government sites, professional societies, patient groups
  - Data can be localized to individual customer catchment areas
American Cancer Society

Cancer Facts & Figures 2009

Estimated number of new cancer cases for 2009, excluding basal and squamous cell skin cancers and in situ carcinomas except urinary bladder.

Note: State estimates are offered as a rough guide and should be interpreted with caution. State estimates may not add to US total due to rounding.
## Screening Guidelines for the Early Detection of Cancer in Average-risk Asymptomatic People

<table>
<thead>
<tr>
<th>Cancer Site</th>
<th>Population</th>
<th>Test or Procedure</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>Women, age 20+</td>
<td>Breast self-examination</td>
<td>Beginning in their early 20s, women should be told about the benefits and limitations of breast self-examination (BSE). The importance of prompt reporting of any new breast symptoms to a health professional should be emphasized. Women who choose to do BSE should receive instruction and have their technique reviewed on the occasion of a periodic health examination. It is acceptable for women to choose not to do BSE or to do BSE irregularly.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical breast examination</td>
<td>For women in their 20s and 30s, it is recommended that clinical breast examination (CBE) be part of a periodic health examination; preferably at least every three years. Asymptomatic women aged 40 and over should continue to receive a clinical breast examination as part of a periodic health examination, preferably annually.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mammography</td>
<td>Begin annual mammography at age 40.*</td>
</tr>
<tr>
<td>Colorectal</td>
<td>Men and women, age 50+</td>
<td>Fecal occult blood test (FOBT) with at least 50% sensitivity for cancer, or fecal immunochemical test (FIT) with at least 50% sensitivity for cancer, or stool DNA test</td>
<td>Annual, starting at age 50*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Flexible sigmoidoscopy, or vitamin A supplement</td>
<td>Every five years, starting at age 50*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fecal occult blood test (FOBT) and flexible sigmoidoscopy or vitamin A supplement</td>
<td>Annual FOBT or fecal immunochemical test (FIT) and flexible sigmoidoscopy every five years, starting at age 50*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Double-contrast barium enema (DCBE), or colonoscopy</td>
<td>Every five years, starting at age 50*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CT colonography</td>
<td>Every five years, starting at age 50*</td>
</tr>
<tr>
<td>Prostate</td>
<td>Men, age 50+</td>
<td>Digital rectal examination (DRE) and prostate-specific antigen test (PSA)</td>
<td>Health care providers should discuss the potential benefits and limitations of prostate cancer early detection testing with men and offer the PSA blood test and the digital rectal examination annually, beginning at age 50, to men who are at average risk of prostate cancer, and who have a life expectancy of at least 10 years.*</td>
</tr>
<tr>
<td>Cervix</td>
<td>Women, age 18+</td>
<td>Pap test</td>
<td>Cervical cancer screening should begin approximately three years after a woman begins having vaginal intercourse, but no later than 21 years of age. Screening should be done every year with conventional Pap tests or every two years using liquid-based Pap tests. At or after age 30, women who have had three normal test results in a row may get screened every two to three years with cervical cytology (either conventional or liquid-based Pap test) alone, or every three years with an HPV (DNA) test plus cervical cytology. Women 70 years of age and older who have had three or more normal Pap tests and no abnormal Pap tests in the past 10 years and women who have had a total hysterectomy may choose to stop cervical cancer screening.</td>
</tr>
<tr>
<td>Endometrial</td>
<td>Women, at menopause</td>
<td>At the time of menopause</td>
<td>At the time of menopause, women at average risk should be informed about risks and symptoms of endometrial cancer and strongly encouraged to report any unexpected bleeding or spotting to their physicians.</td>
</tr>
</tbody>
</table>
| Cancer-related checkup | Men and women, age 20+ | On the occasion of a periodic health examination, the cancer-related checkup should include examination for cancers of the thyroid, testicles, ovaries, lymph nodes, oral cavity, and skin, as well as health counseling about tobacco, sun exposure, diet and nutrition, risk factors, sexual practices, and environmental and occupational exposures.
# Macro costing

## Estimated Direct and Indirect Costs (in Billions of Dollars) of CVD and Stroke: United States: 2009

<table>
<thead>
<tr>
<th></th>
<th>Heart Diseases*</th>
<th>Coronary Heart Disease</th>
<th>Stroke</th>
<th>Hypertensive Disease</th>
<th>Heart Failure</th>
<th>Total Cardiovascular Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Direct costs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital</td>
<td>$106.3</td>
<td>$54.6</td>
<td>$20.2</td>
<td>$8.2</td>
<td>$20.1</td>
<td>$150.1</td>
</tr>
<tr>
<td>Nursing home</td>
<td>$23.4</td>
<td>$12.3</td>
<td>$16.2</td>
<td>$4.8</td>
<td>$4.5</td>
<td>$48.2</td>
</tr>
<tr>
<td>Physicians/other professionals</td>
<td>$23.8</td>
<td>$13.4</td>
<td>$3.7</td>
<td>$13.4</td>
<td>$2.4</td>
<td>$46.4</td>
</tr>
<tr>
<td>Drugs/other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical durables</td>
<td>$22.1</td>
<td>$10.3</td>
<td>$1.4</td>
<td>$25.4</td>
<td>$3.3</td>
<td>$52.3</td>
</tr>
<tr>
<td>Home health care</td>
<td>$7.4</td>
<td>$2.2</td>
<td>$4.4</td>
<td>$2.4</td>
<td>$3.4</td>
<td>$16.8</td>
</tr>
<tr>
<td>Total expenditures</td>
<td>$183.0</td>
<td>$92.8</td>
<td>$45.9</td>
<td>$54.2</td>
<td>$33.7</td>
<td>$313.8</td>
</tr>
<tr>
<td><strong>Indirect costs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lost productivity/morbidity</td>
<td>$24.0</td>
<td>$10.6</td>
<td>$7.0</td>
<td>$8.4</td>
<td>...</td>
<td>$39.1</td>
</tr>
<tr>
<td>Lost productivity/mortality</td>
<td>$97.6</td>
<td>$62.0</td>
<td>$16.0</td>
<td>$10.8</td>
<td>$3.5*</td>
<td>$122.4</td>
</tr>
<tr>
<td><strong>Grand totals</strong></td>
<td>$304.6</td>
<td>$165.4</td>
<td>$68.9</td>
<td>$73.4</td>
<td>$37.2</td>
<td>$475.3</td>
</tr>
</tbody>
</table>
The 15 leading causes of death in 2007
1. Diseases of heart
2. Malignant neoplasms
3. Cerebrovascular diseases
4. Chronic lower respiratory diseases
5. Accidents (unintentional injuries)
6. Alzheimer’s disease
7. Diabetes mellitus
8. Influenza and pneumonia
9. Nephritis, nephrotic syndrome and nephrosis
10. Septicemia
11. Intentional self-harm (suicide)
12. Chronic liver disease and cirrhosis
13. Essential hypertension and hypertensive renal disease
14. Parkinson’s disease
15. Assault (homicide)
Source: Division of Vital Statistics
Depending on device, sample micro feasibilities need to be done

- Device is highly specialized to specific disease types
- Device is relatively costly
- Need for hospital/clinic/physician to economically justify
- Need to determine size and specialty of hospital
Typical hospital catchment area

Primary, Secondary, Tertiary
Hospital view of market

<table>
<thead>
<tr>
<th></th>
<th>Population</th>
<th>Estimate of Cases</th>
<th>Suitable</th>
<th>Capture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>3,624,754</td>
<td>16,768</td>
<td>400</td>
<td>100</td>
</tr>
<tr>
<td>Secondary</td>
<td>5,693,800</td>
<td>26,878</td>
<td>650</td>
<td>80</td>
</tr>
<tr>
<td>Tertiary</td>
<td>11,663,544</td>
<td>54,673</td>
<td>1275</td>
<td>20</td>
</tr>
</tbody>
</table>

How much revenue is this?
Specifics of medical market revenue

- Price (to patient) determined by LCA (Lowest Cost Alternative) for replacement technologies
- Price for technologies with increased medical evidence can charge more. But medical evidence needs to be proved. This can be expensive
- Performing the procedure more precisely is not justification.
- Need to prove better results and/or less complications
- Saving time and eliminating errors may cause hospital to purchase without more reimbursement
- How is reimbursement determined?
Specifics of medical market

- Most medical devices require FDA review

Hold for after reimbursement discussion

FDA Clearance/Approval is needed prior to any reimbursement
What’s involved in reimbursement process

- Coverage
  Process of getting a service or procedure included in an insurer’s package

- Coding
  Process of getting a service or a procedure an “identifier” so that it can be priced as a service or bundled with another procedure that is priced

- Payment
  Process by the insurer to set a price for the service or procedure
Reimbursement Overview

Coverage
- National or Local Medicare or Private Payers Evidence Requirements
  - 3 months - 5 years

Coding
- ICD-9, CPT, HCPCS Yearly Revisions
- Market/Evidence Requirements
  - 15 months - 27 months

Payment
- DRGs, APCs, RVUs, ...
- Yearly Revisions
- Add-On/Pass-Through Criteria
  - 2+ years

15 months - 5 years

Source: The Lewin Group, 2001
# Proton Beam Radiation Therapy Codes

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77520</td>
<td>Proton treatment delivery; simple w/o compensation</td>
</tr>
<tr>
<td>77522</td>
<td>Proton treatment delivery; simple w/ compensation</td>
</tr>
<tr>
<td>77523</td>
<td>Proton treatment delivery; intermediate</td>
</tr>
<tr>
<td>77525</td>
<td>Proton treatment delivery; complex</td>
</tr>
</tbody>
</table>
Annual Publication of CPT Coding

Tuesday, November 18, 2008

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 416, and 419
Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payment Rates; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants—Clarification of Provider and Supplier Termination Policy Medicare and Medicaid Programs; Changes to the Ambulatory Surgical Center Conditions for Coverage; Final Rule
New MAC Jurisdictions

Source: CMS
## Proton Beam Procedures

<table>
<thead>
<tr>
<th>CPT</th>
<th>2007 Medicare Physician Fee Schedule (Free-Standing Facility)</th>
<th>2007 APC Payment (Hospital Outpatient)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Global Indiana</td>
<td>Global Florida</td>
</tr>
<tr>
<td>77520</td>
<td>-</td>
<td>$901</td>
</tr>
<tr>
<td>77522</td>
<td>$516</td>
<td>$932</td>
</tr>
<tr>
<td>77523</td>
<td>$782</td>
<td>$968</td>
</tr>
<tr>
<td>77525</td>
<td>$782</td>
<td>$1,108</td>
</tr>
</tbody>
</table>
# OPPS Payment—CY 2007 - CY 2008
## Proton Beam Therapy

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>CY 2007 APC</th>
<th>CY 2008 APC</th>
<th>Per Cent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>77520</td>
<td>$1,161.29</td>
<td>$816.59</td>
<td>-29.7%</td>
</tr>
<tr>
<td>77522</td>
<td>77523</td>
<td>77525</td>
<td></td>
</tr>
<tr>
<td>77522</td>
<td>$1,389.37</td>
<td>$977.09</td>
<td>-29.7%</td>
</tr>
<tr>
<td>77525</td>
<td>$1,161.29</td>
<td>$816.59</td>
<td>-29.7%</td>
</tr>
</tbody>
</table>
Result is a reimbursement schedule from ONE insurer!
Medicare

- CMS administers both Medicare & Medicaid
  - The largest single health purchaser in the world
    - FY 2003 total outlays of $435 billion
    - Responsible for close to 40 cents of every health dollar spent in the US in FY 2002
### TABLE:
**Showing Market Concentration of Privately Insured Individuals in the U.S.**

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company Name</th>
<th>Total Enrollment¹ (Mil)</th>
<th>Cumulative</th>
<th>Percent</th>
<th>Cumulative %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1)</td>
<td>WellPoint</td>
<td>35</td>
<td>35</td>
<td>18.9%</td>
<td>18.9%</td>
</tr>
<tr>
<td>2)</td>
<td>UnitedHealth Group</td>
<td>32.9</td>
<td>67.9</td>
<td>17.8%</td>
<td>36.7%</td>
</tr>
<tr>
<td>3)</td>
<td>Aetna</td>
<td>17.7</td>
<td>85.6</td>
<td>9.6%</td>
<td>46.2%</td>
</tr>
<tr>
<td>4)</td>
<td>Humana</td>
<td>14.8</td>
<td>100.4</td>
<td>8.0%</td>
<td>54.2%</td>
</tr>
<tr>
<td>5)</td>
<td>HealthCare Service Corp</td>
<td>12.4</td>
<td>112.8</td>
<td>6.7%</td>
<td>60.9%</td>
</tr>
<tr>
<td>6)</td>
<td>Cigna Group</td>
<td>12.0</td>
<td>124.8</td>
<td>6.5%</td>
<td>67.4%</td>
</tr>
<tr>
<td>7)</td>
<td>KFHP (Kaiser Foundation)</td>
<td>8.6</td>
<td>133.4</td>
<td>4.6%</td>
<td>72.1%</td>
</tr>
<tr>
<td>8)</td>
<td>Highmark</td>
<td>4.8</td>
<td>138.2</td>
<td>2.6%</td>
<td>74.7%</td>
</tr>
<tr>
<td>9)</td>
<td>Health Net</td>
<td>3.7</td>
<td>141.9</td>
<td>2.0%</td>
<td>76.7%</td>
</tr>
</tbody>
</table>

Total of Top Ten Insurance Firms: 141.9
Total of All Privately Insured Individuals²: 185.1

¹ Source: Company filings, public sources
# The Hospital’s Customers (Patients)

<table>
<thead>
<tr>
<th>Payer Mix &amp; Reimbursement Level</th>
<th>Payment as % of Gross Billing</th>
<th>% of Patient Volume</th>
<th>Gross Billing Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>100%</td>
<td>35.0%</td>
<td></td>
</tr>
<tr>
<td>Managed Care</td>
<td>150%</td>
<td>20.0%</td>
<td></td>
</tr>
<tr>
<td>Commercial</td>
<td>135%</td>
<td>20.0%</td>
<td></td>
</tr>
<tr>
<td>Self Pay</td>
<td>200%</td>
<td>10.0%</td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>100%</td>
<td>10.0%</td>
<td></td>
</tr>
<tr>
<td>Charity</td>
<td>0%</td>
<td>4.0%</td>
<td></td>
</tr>
<tr>
<td>Other (e.g. Personnel)</td>
<td>100%</td>
<td>1.0%</td>
<td></td>
</tr>
<tr>
<td>Payor</td>
<td>Patient Numbers</td>
<td>Factor based on Medicare</td>
<td>Charge per patient</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
<td>--------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Medicare</td>
<td>350</td>
<td>100%</td>
<td>$80.00</td>
</tr>
<tr>
<td>Managed Care</td>
<td>200</td>
<td>150%</td>
<td>$120</td>
</tr>
<tr>
<td>Commercial</td>
<td>200</td>
<td>135%</td>
<td>$108</td>
</tr>
<tr>
<td>Self Pay</td>
<td>100</td>
<td>200%</td>
<td>$160</td>
</tr>
<tr>
<td>Medicaid</td>
<td>100</td>
<td>100%</td>
<td>$80</td>
</tr>
<tr>
<td>Charity</td>
<td>40</td>
<td>0%</td>
<td>$0</td>
</tr>
<tr>
<td>Other (e.g. Personnel)</td>
<td>10</td>
<td>100%</td>
<td>$80</td>
</tr>
</tbody>
</table>

Average Revenue per patient=$ 98,400/1,000 = $98.40
Proton Beam Therapy and the Convoluted Pathway to Incorporating Emerging Technology into Routine Medical Care in the United States

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Abstract: The pathway that emerging medical technologies take to incorporation into routine medical care in the United States is a product of the social, economic, and political milieu. Our review explores how this milieu brought the incorporation of proton beam therapy into the healthcare delivery system to its current point. We look at how new technologies are presently accepted into this system and discuss the emerging trends—such as the use of evidence-based assessment of technology, coverage with evidence policies, and comparative effectiveness analysis—that are affecting proton beam therapy’s effort to find its place in the pantheon of available medical treatments for patients with cancer.

Key Words: technology assessment, biomedical, proton beam therapy, emerging medical technology, evidence-based medicine
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One of the most contentious and controversial issues for health policy decision makers, medical providers, and the healthcare technology industry in the United States is the pathway for incorporating new and emerging medical technologies into the healthcare delivery system. And one of the medical technologies that has economic, and political milieus brought the issue of the incorporation of PBT into the healthcare delivery system to this point. We look at how new technologies are currently accepted into this system and discuss emerging trends—such as the use of evidence-based assessment of technology, coverage with evidence policies, and comparative effectiveness analysis—affecting PBT’s effort to find its place in the pantheon of available medical treatments for patients with cancer.

THE CURRENT HEALTH POLICY CONTEXT
Serious challenges face the United States healthcare delivery system, including the fact that despite ever-increasing healthcare costs, the United States has not yet been able to achieve health outcomes as good as or as high value as those of other industrialized countries.1 Moreover, this confounding situation continues while the number of medically uninsured in the United States grows. To date, most health policy experts agree that the United States has not coherently embraced policies and processes to simultaneously enhance value and address cost.1

The drivers of the rising cost of U.S. healthcare are often portrayed as fraud and abuse, bureaucratic inefficiencies, and inadequate free market influences in the business of healthcare delivery.
What are the important drivers to gain acceptance/reimbursement?

- FDA Clearance/Approval
- Lower diagnostic or treatment cost
- Evidence based results
- Reduce complications
- Reduce hospital stay
- Increase throughput
- Reduce return admissions
- Help an existing company enter market or increase share
Move to integrated approach
Medical Imaging in the Age of Theranostics & Pharmacogenomics

- healthcare dollars spend on diagnostics: from < 1% to 5%?

Predisposition profiling (genetic testing, e.g. DNA Chips)

Screening (PoC incl. Medical Imaging)

Prevention (vaccines, behavior)

Diagnostics (IVD & Medical Imaging)

Treatment selection (Pharmacogenomics & Medical Imaging)

Treatment monitoring (IVD & Medical Imaging)

THERAPY
Image guidance for minimal-invasive therapy

*market forecast (2000), Clinica reports
Drive on to Motivate Hospitals to Prevent Avoidable Readmissions

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One approach is to bundle payments to hospitals, physicians, labs, and other providers

Momentum is building around a new effort to drive down existing rates of hospital readmissions. Different reimbursement proposals to encourage hospitals and physicians to reduce current readmission rates will likely also change the reimbursement status quo for laboratory testing. For example, bundling Part A and Part B payments may be one approach.

Experts increasingly believe one game changer in lowering healthcare costs and improving outcomes is avoidable hospital readmissions. One in five Medicare patients returns to the hospital within 30 days. Overall, readmissions cost Medicare an estimated $17 billion yearly. Of this total, about $12 billion are believed to be avoidable cases.
All this in a regulated environment

May 28, 1976, the Medical Device Amendments to the Food, Drug and Cosmetic Act were enacted into Law.
Device Intended for Human Use

Before a device can be used on humans it must have one of the following:

- 1. Premarket Notification [510(k)] Clearance from FDA
- 2. Premarket Approval Application (PMA) approved by FDA
- 3. Investigational Device Exemption (IDE) approved by FDA or an Investigational Review Board (IRB)
FD&C Act: The LAW

- Prohibition of Adulteration: 501 FD&C Act
- Prohibition of Misbranding: 502 FD&C Act
- Banned devices: 516 FD&C Act
- Notification, and repair, replacement or refund: 518 FD&C Act
- Records and Reports: 519 FD&C Act
- Restricted Devices: 520 FD&C Act
FD&C Act: The LAW

- Establishment Registration & Device Listing: 21 CFR 807
- Premarket Notification [510(k)]: 21 CFR §807.81
- Investigational Device Exemption (IDE): 21 CFR 812
- Quality System Regulation (CGMP): 21 CFR 820
- Labeling: 21 CFR 801
- Medical Device Reporting: 21 CFR 803
- Reports of Corrections and Removals: 21 CFR 806
- Electronic Records; Electronic Signatures: 21 CFR 11
- Device Identification & Classification: 21 CFR 862-892
- RHSA, Electronic Product Radiation: 21 CFR 1000-1050
21 CFR Sec. 820.30 Design controls.
…shall establish and maintain procedures…

(a) General.
(b) Design and development planning.
(c) Design input.
(d) Design output.
(e) Design review.
(j) Design history file.
(i) Design changes.
(h) Design transfer.
(g) Design validation.
(f) Design verification.
Back to the start of the design...  
Time to review a few key points

- Medical market is robust with room for new innovations
- Medical market requires an understanding of reimbursement
- Medical market is well defined for estimating potential sales
- Evidence based medicine requires a lengthy process
- Regulatory issues are extensive but well documented